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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,649	07/01/2003	Chris Rundfeldt	NY-HUBR 1221-US	2085

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/611,649	RUNDFELDT ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15,17,18 and 20-23* is/are pending in the application.

4a) Of the above claim(s) *5 and 7* is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-4,6,8-13,15,17-18 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/07/05, 12/04/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application filed on 07/01/2003 claims benefit of 60/395,221, filed on 07/11/2002.

Applicant's amendment filed on 07/26/2006, wherein claims 3, 15, 17, 20 have been amended, and claims 14, 16, 19 have been canceled. Applicant's amendment also added new claims 22-23.

Note that applicant has further amended claim 1 on 12/05/2006 to include the elected species.

Claims 1-13, 15, 17-18, 20-23 are pending.

Election/Restrictions

Claims 5, and 7 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicant's election of invention Group II, Claims 1-3 (in part), 4 (in part), 6 (in part), 8-12 (in part), 13, 15 (in part), 17-18 (in part), 20-21 (in part), drawn to a method for the treatment of a skin disease comprising topically administering a compound of formula (I) or a pharmaceutically acceptable salt thereof, wherein R1 is C1-12-alkyl, straight-chain or branched-chain or –C2-C12 alkenyl, mono-or polyunsaturated as in claim 1, (i), and R5 is a mono-, bi- or tricyclic saturated or mono- or polyunsaturated heterocycle having 5-15 ring members and 1-6 heteroatoms claims 36-53 in reply filed on 07/26/2006 is acknowledged. Applicant's elect (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide as a species.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is therefore made FINAL.

Claims 1-4, 6, 8-13, 15, 17-18, 20-23 are examined herein as they read on the elected invention, and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because claim 17 depends on a canceled claim 16. Thus, it is not clear as to the dependency of claim 17.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 8-13, 17-18, 20-21, 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of specific skin

disease, does not reasonably provide enablement for **treatment of any skin disease in general** in a subject comprising topically administering a compound (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The rejected claims are drawn to a method for the treatment of a skin disease comprising topically administering (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide.

(2) The breadth of the claims:

The claims are very broad. The claims are drawn to method of treating any skin disease in a subject. The coverage of diseases in the claim is immense. The breadth of the claims includes hundreds of diseases such as skin cancer, psoriasis etc.

(3) The state of the prior art / (4) The relative skill of those in the art::

The relative skill of those in the art is high with respect to a specific skin disease comprising topically administering a compound (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide.

(5) The amount of direction or guidance presented / (6) The presence or absence of working examples:

All the guidance and examples provided in the specification is for the treatment of allergic dermatitis by administration of AWD 12-281. See instant specification page 21, lines 13-16.

(7) The predictability or unpredictability of the art:

Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839 (1970). The skin ailments claimed in the instant invention will have different etiologies (See The Merck Manual, Fifteenth Edition, pages 2247-2276, 2294-2295). It is well-known in the state of the art that the cause of dry skin and or signs of skin aging and/or skin pigmentation is multifactorial, that is, there are several factors whose combined effects produce dry skin. For example, dry skin may result from age related changes, environmental factors such as exposure to sun, cold, chemicals,

cosmetics, detergents etc. or other irritants. Moreover many skin diseases such as skin cancers (skin pigmentations) are very difficult to treat, despite the fact that there are many drugs, which can be used. Thus the skilled artisan would view that the **treatment** of any skin disease in a patient in need of such treatment is highly unpredictable using the compound (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide.

(8) The Quantity of Experimentation Necessary:

Since every disease and disorder has its unique chemical pathway of expression, diagnosis and treatment of individual diseases and condition cannot be predicted a priori but must be determined from case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine if thecompound of (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide treats which diseases/conditions. Considering the multitude of different diseases to be treated, this is a very large degree of experimentation.

Therefore, Applicant fails to provide information sufficient to practice the claimed invention, absent **undue experimentation**.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to test (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide in the instant methods of the particular treatments herein, with no assurance of success.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific pharmaceutical agent that stimulates cAMP production in combination with (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide in the method for treatment of a specific skin disease, does not reasonably provide enablement for **any substance or compounds represented by** pharmaceutical agent that stimulates cAMP production **in general**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention **commensurate in scope** with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples;

and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate." The CAFC further clearly states '[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure. formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405 (emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. ' A definition by function, as we have previously indicated, does not suffice to define the genus ..." at 1406 (empahasis added).

In the instant case, "drug that stimulates cAMP production" recited in the instant claims is purely a functional distinction. Hence, these functional recitations read on any compounds that might have recited functions. However, the specification merely provides a limited number of examples of compounds for the various kinds of functional compounds possible.

Thus, Applicant's functional language at the points of novelty fail to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicant's, neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited monopoly asserted." *Genera/ Electric Co. v. Wabash Appliance Corp*. 37 USPQ at 468 (US 1938).

(1) The nature of the invention:

The rejected claim is drawn to a method for the treatment of a skin disease comprising topically administering (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide in combination with any drug that stimulates cAMP production.

(2) The breadth of the claims:

The claim is very broad. The claim is drawn to a method of treating any skin disease in a subject by administering (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide in combination with any drug that stimulates cAMP production.

(3). Guidance of the Specification / (4) Working Examples:

The guidance given by the specification as to what type of drugs that stimulate cAMP production can be used in combination with (N-3, 5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide for the treatment of skin diseases is limited. See page 10, lines 13-19 of instant specification. The specification does not

provide any working example with a drug that stimulate cAMP production in combination with N-3, 5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide in the method of treatment of skin disease.

(5). State of the Art:

While the state of the art is relatively high with regard to specific drug that stimulates cAMP production in combination with N-3, 5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide in the method of treatment of skin disease the state of the art with regard to any drug that stimulates cAMP production in general is underdeveloped. Different drug that stimulates cAMP production have different chemical structures and are expected to behave in different manners, evidence that the level of skill in this art is low relative to the difficulty of the task of determining a suitable drug that stimulates cAMP production in combination with N-3, 5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide in the method of treatment of skin disease.

(6). Predictability of the Art:

The invention is directed to drug that stimulates cAMP production in general in combination with N-3, 5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide for the treatment of a skin disease. It is well established that "the scope of enablement various inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839 (1970).

It is further noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. One skilled in the art would recognize that it is highly unpredictable with regards to not only therapeutic effects, but also side effects, and especially serious toxicity due to drug accumulation or that may be generated by drug-drug interactions when and/or after administering to a host any agents represented by a drug that stimulates cAMP production and/or while the patient also administers other medicines. One of skill in the art would not be able to fully predict the possible treatment of a skin disease herein and possible adverse effects occurring with many agents having the claimed functional properties. Thus, the instant claimed invention is highly unpredictable.

(7). The Quantity of Experimentation Necessary:

In order to practice the claimed invention, one of skill in the art would have to first envision a specific drug that stimulates cAMP production, a pharmaceutical carrier, a dosage for each drug that stimulates cAMP production, the duration of treatment, route of treatment, etc. One of skill in the art would then need to test specific drug that stimulates cAMP in the model system to determine whether or not it is effective for treating a specific skin disease and one would need to test for side effects and toxicity. If the treatment is unsuccessful, one of skill in the art would have to modify the first drug that stimulates cAMP production, dosage, duration of treatment, route of administration, etc. Even if successful, however, one of skill in the art would then need to determine the magnitude of the side effects and toxicity of utilizing drug that stimulates cAMP production. One of skill in the art would then need to determine whether or not the

magnitude of the side effects could be reduced by increasing or decreasing the dosage of drug that stimulates cAMP production while retaining the functional aspect. Once the functionality to toxicity ratio was maximized, one of skill in the art would need to determine whether or not the drug that stimulates cAMP production which had been used was of sufficient benefit that it would serve as useful for treating a specific skin disease when administered in combination with N-3, 5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-iH-indol-3yl]-2-oxoacetamide. If not, one would need to select another drug that stimulates cAMP production and repeat the process until a sufficient benefit to detriment ratio had been achieved.

Genetech, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 6, 8-13, 15, 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofgen et al. (US 6, 251, 923, PTO-1449).

Hofgen et al. discloses hydroxyindoles of the Formula (I), including the instantly elected species (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the treatment of skin diseases such as psoriasis, keratosis, atopic dermatitis (allergic dermatitis). See abstract; column 7, lines 25-34; column 10, EXAMPLE 1. Oily suspensions for topical application comprising other agents such as fatty acid esters is also taught. See column 8, lines 43-45.

Thus, Hofgen et al. anticipate instant claims 1-4, 6, 8-13, 15, 22-23.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 6, 8-13, 15, 17-18, 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Baumer et al. (European Journal of Pharmacology, 446, 2002, pages 195-200, PTO-1449).

Baumer et al. disclose the employment of AWD 12-281 ((N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide) to treat allergic dermatitis in mice. To obtain an allergic dermatitis, BALB/c mice were sensitized to toluene-2,4-diisocyanate (TDI). TDI challenged mice were treated by topically applying AWD 12281 (0.1-3 %). It is disclosed that AWD 12-281 inhibited the ear swelling significantly 8, 16, 24, and 48 h after the challenge. See abstract; page 196, right-hand

column, paragraph 2-page 197, right-hand column, paragraph 1; page 198, left-hand column, last paragraph-page 199, paragraph 1.

Thus, Baumer et al. anticipate instant claims 1-4, 6, 8-13, 15, 17-18, 22.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 6, 8-13, 15, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ehinger et al. (NAUNYN-SCHMIEDEBERG'S ARCHIVES OF PHARMACOLOGY, vol. 363, no.4 Supplement, 2001, page R85, XP009019486 42nd Spring Meeting of the German Society for Experimental and Clinical Pharmacology and Toxicology; Mainz, Germany; March 13-15, 2001, PTO-1449).

Ehinger et al. disclose the employment of AWD 12281 ((N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide) to treat atopic dermatitis. Experiments with toluene-2,4-diisocyanate (TDI)-sensitized mice was disclosed. TDI challenged mice were treated by topically applying AWD 12281 (0.1-3 %). See the entire paper).

Thus, Ehinger et al. anticipate instant claims 1-4, 6, 8-13, 15, 22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable Ehinger et al. as applied to claims 1-4, 6, 8-13, 15, 22 above, in view of Winger (US 5,767,095, PTO-892).

Ehinger et al. is as discussed above.

Ehinger et al. does not teach the employment of a pharmaceutical agent, corticosteroid in combination with AWD 12281 in the method of treating atopic dermatitis.

Winger teaches that corticosterioids are known for the treatment of canine atopic dermatitis. See column 25, lines 19-22.

It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Ehinger and Winger the instant claims contain two compounds used for treatment of skin condition such as atopic dermatitis. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, 8-13, 17-18, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-29, 36-38 of co-pending Application No. 10/856034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of treating skin disease comprising topically administering N-(3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide, and '034 is drawn to a method of treating atopic dermatitis comprising administering a compound, N-(3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide. The application '034 does not specifically teach the topical administration of the compound in the method therein. It would have been obvious to

the person of ordinary skill in the art at the time of invention to administer topically to a subject a therapeutically effective amount of N-(3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide with reasonable expectation of treating a skin disorder. Further, topical administration of compounds such as topical is well known for treating skin disorders.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER